In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 19-0241V UNPUBLISHED

Petitioner,
v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent.

Chief Special Master Corcoran

Filed: August 10, 2020

Special Processing Unit (SPU); Findings of Fact; Onset; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Carol L. Gallagher, Somers Point, NJ, for petitioner.

Camille Michelle Collett, U.S. Department of Justice, Washington, DC, for respondent.

FINDINGS OF FACT¹

On February 12, 2019, Temperature Report filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et seq.² (the "Vaccine Act"). Petitioner alleges that she suffered a left shoulder injury after receiving the influenza ("flu") vaccine on October 2, 2017. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

For the reasons discussed below, I find the onset of Petitioner's shoulder injury related to vaccine administration ("SIRVA") occurred within 48 hours of vaccination. Specifically, Petitioner more likely than not suffered pain immediately upon vaccination

¹ Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Relevant Procedural History

On April 30, 2020, Petitioner filed the last of her required medical records and a statement of completion. ECF Nos. 28-29. On June 5, 2020, Respondent filed a status report indicating he "intends to continue to defend this case." ECF No. 30. He requested 60 days to file his Rule 4(c) Report. *Id.* In that Report (filed on August 6, 2020), Respondent argues that Petitioner's injury does not meet the Table definition of SIRVA because she has not established that the onset of her left shoulder pain occurred within 48 hours of vaccination. ECF No. 31.

II. Issue

At issue is whether Petitioner's first symptom or manifestation of onset after vaccine administration (specifically pain) occurred within 48 hours as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation ("QAI") for a Table SIRVA. 42 C.F.R. § 100.3(a) XIV.B. (2017) (influenza vaccination); 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the Qualifications and aids to interpretation ("QAI")).

III. Authority

Pursuant to Vaccine Act § 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act § 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. § 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for

inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

I make these findings after a complete review of the record, including all medical records, affidavits, testimony, expert reports, Respondent's Rule 4(c) Report, and additional evidence filed. They are as follows:

 Prior to vaccination, Petitioner was treated for some generalized aches and pains, difficulty breathing, and an episode of chest pain in 2014 (Ex. 3 at 13-14), dermatitis and right knee pain in 2016 (Ex. 5), and varicose veins and a heart murmur in 2016-17 (Ex. 3 at 5-12). There is no evidence she experienced any prior left shoulder pain.

- Petitioner visited her primary care provider ("PCP") for an annual physical on October 2, 2017, the same day she received the flu vaccine alleged as causal. Ex. 3 at 5-6. At that visit, she discussed some abnormal EKG results with her PCP and expressed concern regarding her varicose veins. *Id.* In her affidavit, Petitioner explained that she was administered the flu vaccine later that day at an area Walgreen's Pharmacy because her PCP clinic had not yet received their flu vaccines. Ex. 2 at ¶¶ 2-3.
- The vaccine record shows the flu vaccine was administered intramuscularly in Petitioner's left deltoid on October 2, 2017. Exs. 1, 9.
- On October 17, 2017, fifteen days after vaccination, Petitioner visited a vascular surgeon for leg pain and swelling she had experienced for the last eight years. Ex. 7 at 1-4. Venous duplex and vein reflux studies were ordered. *Id.* at 4. These studies were performed on October 20, 2017. *Id.* at 5-9. There is a notation of "no pain" in the medical record from this October 17, 2017 visit (*id.* at 3), but the information under extremities shows the vascular surgeon was focused on Petitioner's lower extremities (*id.* at 4). There is also an entry under musculoskeletal which indicates Petitioner "[d]enies back pain, sciatica, arthritis, knee pain and foot pain," but no entry regarding the lack or existence of shoulder pain. *Id.* at 2.
- Petitioner first sought treatment for her left shoulder pain from her PCP on January 19, 2018, approximately three and one-half months after vaccination. Ex. 3 at 3-4. At this visit, she complained of left shoulder pain following her flu shot and a cyst on the right side of her neck. *Id.* at 3. Her PCP recommended that she take Tylenol and follow-up in a few months. *Id.* at 4.
- Petitioner visited an orthopedist on June 11, 2018, now approximately eight months since vaccination. Ex. 4 at 8. At this visit, Petitioner indicated she "had left shoulder pain ever since a flu shot in October 2017." *Id.* Petitioner was diagnosed with left shoulder impingement and administered a steroid injection. *Id.* Additionally, she was instructed to attend physical therapy ("PT"). *Id.* at 6.
- Petitioner attended PT from July 2 through August 10, 2018. Ex. 11 at 1-6.
 On her intake form, she again indicated that her left shoulder pain started in October after the flu shot. *Id.* at 2.

- Petitioner returned to the orthopedist on October 25, 2018. Ex. 4 at 7. She
 indicated she had obtained some relief from the cortisone injection but still
 had pain with daily activities and when sleeping. An MRI was ordered. *Id.*
- The MRI performed on November 13, 2018 revealed a "[h]igh-grade bursal surface tear of the supraspinatus tendon." Ex. 4 at 9; Ex. 6 at 7 (record of MRI from directly from University Radiology).
- Petitioner was seen again by her PCP for her annual physical on November 30, 2018. Ex. 3 at 1-2. He noted that she was receiving orthopedic treatment for her left shoulder pain which started after she received a flu shot on October 2, 2017. Id. at 1.

The above medical entries show that Petitioner consistently associated the origin of her left shoulder pain to the flu vaccine she received on October 2, 2017. Every time she sought treatment for her left shoulder pain from her PCP, orthopedist, and physical therapist, Petitioner described her pain as occurring contemporaneously with the flu shot. In her affidavit, she described pain after receiving the flu shot which became significant by that night. Ex. 2 at ¶¶ 4, 6.

Respondent stresses that Petitioner did not complain of her left shoulder pain when she visited a vascular surgeon on October 17, 2017. Rule 4(c) Report at 6. However, the purpose of this visit was treatment for leg pain and swelling, which she has suffered from over the last eight years. Given the length of time she had experienced these symptoms and the specific expertise of this treating physician, Petitioner's failure to mention left shoulder pain related to a recently administered flu vaccine is understandable – as is this treater's focus on her leg rather than arm.

Respondent also emphasizes that Petitioner did not seek medical care for her left shoulder pain until three and one-half months after vaccination. Rule 4(c) Report at 5-6. However, it is often common for a SIRVA petitioner to delay treatment, thinking his/her injury will resolve on its own. As Respondent himself notes, when Petitioner did seek medical treatment, in January 2018, it appears that the initial level of her pain was not yet severe (even if persistent since vaccination). *Id.* at 6. Her PCP prescribed only Tylenol to control her pain. Ex. 3 at 4. It is not unreasonable for Petitioner to have waited this amount of time before seeking treatment for her SIRVA.

Accordingly, I find there is preponderant evidence to establish the onset of Petitioner's pain occurred within 48 hours of vaccination. Specifically, I find the onset of Petitioner's pain immediately upon vaccination.

V. Scheduling Order

In light of this fact ruling, Respondent should review the record in this case again and should indicate whether he is willing to engage in settlement discussions, desires to

file an amended Rule 4(c) Report conceding entitlement, or wishes to continue to defend this case. If the later, he should indicate the bases for his continued objection to compensation in this case.

Respondent shall file a status report providing his tentative position given my fact ruling by no later than <u>Thursday</u>, <u>September 10</u>, <u>2020</u>.

Petitioner should finalize a demand and should forward her demand and supporting documentation to Respondent as soon as possible. She also should file any updated medical records or other evidence needed to establish her current condition.

Petitioner shall file a status report updating me on the status of her demand and supporting documentation by no later than <u>Thursday</u>, <u>September 10</u>, <u>2020</u>.

IT IS SO ORDERED.

<u>s/Brian H. Corcoran</u> Brian H. Corcoran

Chief Special Master